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COLOPLAST A/S			ORWIG, KEVIN S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/581,040	Applicant(s) HANSEN ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A: Translation of JP 10033655</u> |

DETAILED ACTION

The amendments and arguments filed May 12, 2010 are acknowledged and have been fully considered. Claims 1-15 are now pending. Claims 1 and 5 are amended; claim 15 has been added. Claims 1-15 are now under consideration.

OBJECTIONS/REJECTIONS WITHDRAWN

The rejection of claims 1-10 under 35 U.S.C. 103(a) over JP402270818 ('818) and JP06199660 ('660) is withdrawn in light of the claim amendments.

The rejection of claims 1-13 under 35 U.S.C. 103(a) over JP402270818 ('818), JP06199660 ('660), and HIRSCH is withdrawn in light of the claim amendments.

Applicants' arguments are moot in light of the new grounds of rejection presented below.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 112 (1st Paragraph)

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response filed May 12, 2010 has introduced NEW MATTER into the claims. Amended claim 1 recites "...the vapour permeability of the patch is greater than 500 g/m²". Amended claim 5 recites "...the vapour permeability of the patch is greater than 500-800 g/m²". Similarly, new claim 15 recites "...the vapour permeability of the patch is between 550-750 g/m²". No support is found in the instant application for the range of vapour permeability greater than 500 g/m², for the range of 500-800 g/m², or for the range of 550-750 g/m². In fact, the values of 500 g/m² and 550 g/m² do not appear anywhere in the application as filed. In the absence of support the specific ranges claimed, the recitations, "...greater than 500 g/m²" in claim 1, "...500-800 g/m²" in claim 5, and "...550-750 g/m²" are new matter and must be removed from the claims.

The response did not point out where support for the amended claims could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Instant claims 1, 5, and 15 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in amended claims 1, 5, and 15, which did not appear in the

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specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. Applicant is required to provide sufficient written support for the limitations recited in present claims 1, 5, and 15 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8-11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over YAMAMOTO (JP 10-033655; Published Feb. 10, 1998; Ref. AN on IDS dated 12/18/06; Machine translation provided herein).

1. Yamamoto discloses topical patch preparations for dermatitis treatment (par. [0009]; claim 1). The patches comprise an adhesive layer laminated onto a base film (i.e. a backing layer), the base film being made of polyurethane that has a thickness of 10-80 μm , preferably 20-50 μm (pars. [0010], [0012], [0014], and [0028]; claims 1 and 2). Yamamoto emphasizes the importance of having a moisture vapor transmission in the range of 300-1500 g/m^2 (pars. [0009], [0010], and [0014]; claim 1). Yamamoto teaches the use of hydrocolloid adhesives (pars. [0031] and [0033]), and teaches that the thickness of the adhesive layer is adjusted to achieve a desired moisture vapor transmission, and is preferably about 30 μm (par. [0014]). Thus, the only difference between Yamamoto and the instant claims is that the range of vapor permeability taught by Yamamoto overlaps with that instantly claimed and Yamamoto is silent with respect to the absorption of the patch.

2. However, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d

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1934 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997). See MPEP § 2144.05.

3. Regarding the absorption and reflectance of the patch, given that the prior art yields a composition that is essentially identical to that applicants are claiming, the prior art product would necessarily possess the claimed properties. Also see *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977), "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established," and *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), "when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."

4. In the instant case, the prior art teaches a patch identical in composition (having a backing layer and an adhesive layer of hydrocolloid particles) and structure (the adhesive layer being of the required thickness) and therefore the burden is properly shifted to applicants to present evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product.

5. It is also noted that on p. 5, par. 3 of the instant disclosure, Applicant relates the amount of absorption to the thickness of the adhesive layer stating, "The idea is the thicker dressing, the more hydrocolloid particles and the higher absorption." Given that the thickness of the adhesive layer taught by the prior art is within the claimed range, and applicants allude to absorption being a function of increasing thickness, the skilled

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artisan would reasonably expect that the absorption of the patch taught by the prior art, if measured, would meet the instantly claimed limitation.

6. Regarding claim 2, embodiment 1 of Yamamoto uses an adhesive layer with a thickness of 40 μm (par. [0028]). Although the reference does not explicitly state that the patch is of a uniform thickness, MPEP 2144.01 states that “in considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” Also see *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). In the instant case, the example taught by the prior art illustrates components having a defined thickness (i.e. 40 μm adhesive layer) applied to a backing film (i.e. 30 μm polyurethane). The skilled artisan would assume that given that the thickness of the components being applied does not vary, the thickness of the overall patch would also not be substantially variable.

7. Regarding claim 11, Yamamoto teaches that the adhesive layer is laminated to the backing film (pars. [0028] and [0031]). Any artisan would understand these teachings to mean that the adhesive layer is uninterrupted.

8. Regarding claim 14, Yamamoto teaches that the patch can further comprise medicines, such as antibacterials, anti-inflammatory agents, cytokines, etc (par. [0024]).

9. Regarding claim 15, the only difference from Yamamoto is the thickness of the adhesive layer. Yamamoto teaches that the thickness of the adhesive layer is adjusted to achieve a desired moisture vapor transmission, and is preferably about 30 μm (par. [0014]). Furthermore, Yamamoto embodies an adhesive layer of 40 μm thickness

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(embodiment 1, par. [0028]). Thus, the artisan would understand that the thickness of the adhesive layer is a result effective variable that can be adjusted. Furthermore, the MPEP states that "a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). There is nothing of record to indicate that a difference of only 10 μm would result in appreciably different properties.

10. Claims 1-5, 8-11, 14, and 15 are rendered obvious by Yamamoto.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto as applied to claims 1-5, 8-11, 14, and 15 above, and further in view of UDAGAWA (JP 06199660; Published Jul. 19, 1994, Ref. AP on IDS dated 12/18/06; translation previously provided by applicant; referred to as '660 in the prior Office Action).

11. The teachings of Yamamoto are presented *supra*. Yamamoto teaches the use of hydrocolloid adhesives (pars. [0031] and [0033]) but is silent as to the particle size of the hydrocolloid components. Thus, the artisan would have looked to the literature for guidance.

12. Udagawa discloses patch preparations with good drug release properties (title). The patches comprise a support such as a polyurethane film (par. [0035], p. 9) and an adhesive layer containing cellulose particles having a size ranging from 1-150 μm (abstract). Udagawa teaches that if the particle size of the cellulose particles is too small, the drug release property is reduced. If the particle size thereof is large, the

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dispersing property of the adhesive is reduced. Therefore, the particle size thereof is preferably 1 to 150 μm , more preferably 10 to 120 μm (par. [0016], p. 5).

13. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use hydrocolloid particles of less than 50 μm . One would have been motivated to do so since Udagawa teaches that particles within this size range are preferable to maintain the drug release and adhesive properties of the patch. Claims 6 and 7 are rendered obvious by Yamamoto and Udagawa.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto as applied to claims 1-5, 8-11, 14, and 15 above, and further in view of HIRSCH (U.S. 3,658,065; Issued Apr. 25, 1972; of record).

14. The teachings of Yamamoto are presented *supra*. Yamamoto does not teach a patch having an absorbent pad or one or more cavities. However, configuring a patch in this way is obvious to any skilled artisan.

15. For example, Hirsch discloses absorbent bandages with an integral reservoir for the storage of fluids (abstract). It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Yamamoto with the absorbent pad and reservoir taught by Hirsch. One would have been motivated to do so because Hirsch teaches that an absorbent pad and reservoir is advantageous because it eliminates the need for frequent replacement of the patch (because the patch is absorbing any wound exudate or sweat from the skin) and further decreases discomfort of the patient. See col. 1, lines 1-19; claim 1.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Summary/Conclusion

Claims 1-15 are rejected. No claims are currently allowable.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin S Orwig/

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